

REMARKS

Initially, Applicants would like to thank Examiner Yu for the courteous and helpful Interview conducted April 28, 2009, during which the subject matter set forth below was discussed.

Claim 1 has been amended by requiring the composition to be stable as well as requiring the presence of the specified glycine derivatives in an amount sufficient to effect such stabilization. Support for these amendments exists throughout the present application, including the examples. For example, page 5, lines 17-18 of the present application states that stable compositions are compositions which do not undergo phase separation and do not release oil. As demonstrated in the Rule 132 declarations submitted in this case, unstable compositions contain large oily globules (resulting from such instability), whereas stable compositions do not. By virtue of the above amendments, the claimed compositions are more specifically directed to the demonstration of superior and improved results set forth in the submitted Rule 132 declarations

Claims 1, 6 and 8-24 are currently pending, although claims 21-24 have been withdrawn from consideration. Upon indication of allowable subject matter, Applicants intend to seek rejoinder of the withdrawn claims as appropriate, particularly claims 21-23 which ultimately depend from claim 1. (See, MPEP 821.04).

The Office Action rejected claims 1, 6, 8-18 and 20 under 35 U.S.C. § 103 as obvious over WO 02/03952 (“Robinson”) in view of U.S. patent application publication no. 20010002257/French patent application no. 2,771,632 (“Stoltz”), and claims 1, 6 and 8-20 under 35 U.S.C. § 103 as obvious over EP 1,055,406/U.S. patent 6,465,402 (“Lorant”) in view of U.S. patent 6,346,255 (“Fontinos”). In view of the following comments, Applicants respectfully request reconsideration and withdrawal of these rejections.

The claims as amended are directed to a specific type of composition (oil-in-water emulsion) having (1) at least 1% of a specific elastomeric compound; (2) capryloylglycine and/or undecylenoylglycine; and (3) a hydrophilic polymer, wherein the composition is stable and the glycine derivative is present in an amount sufficient to effect such stabilization. The applied art neither teaches nor suggests such specific, stabilized emulsions.

As noted in the Background section of the present application, oil-in-water emulsions containing at least 1% elastomeric organopolysiloxane and hydrophilic polymer(s) tend toward destabilization. (See, page 5 of the present application). Applicants have discovered that adding capryloylglycine and/or undecylenoylglycine to oil-in-water emulsions containing at least 1% of a specific type of elastomeric organopolysiloxane and hydrophilic polymer(s) improves stability of the emulsions. For example, examples 3-6 of the present application, demonstrate that emulsions containing the claimed glycine derivatives are stable, whereas emulsions lacking the required glycine derivatives are not. Similarly, the Rule 132 declarations submitted July 24, 2007, and November 1, 2006, demonstrate that emulsions containing the claimed glycine derivatives are stable, whereas emulsions containing different amino acid compounds (including glycine itself) are not.

The data in both the examples of the present application and the Rule 132 declarations submitted in this case demonstrate that the claimed glycine derivatives can stabilize oil-in-water emulsions containing at least 1% elastomeric organopolysiloxane and hydrophilic polymer(s), and that such stabilization was surprising and unexpected given the instability of and presence of large oily globules in extremely similar compositions. (See, Rule 132 declaration submitted November 1, 2006, at par. 9, and Rule 132 declaration submitted July 24, 2007, at par. 7). Based on this information alone, Applicants respectfully submit that the pending rejections are improper and should be withdrawn.

That is, even assuming that a *prima facie* case of obviousness has been set forth (which, as explained below, is not the case), Applicants have rebutted such a hypothetical case of obviousness with their showing of unexpected and surprising stability of the claimed oil-in-water emulsions, and by their narrowing the claims to be commensurate in scope with their showing of unexpected and surprising results.

This is particularly true for claims 12-14 which are directed to specific hydrophilic polymers.

For at least this reason Applicants respectfully submit that the pending rejections under 35 U.S.C. § 103 should be reconsidered and withdrawn.

Furthermore, no *prima facie* case of obviousness exists. Of particular note in this regard is the fact that none of the applied art teaches, suggests or recognizes that the required glycine derivatives can be added in an amount sufficient to stabilize an emulsion. Rather, the applied art generally suggests that such glycine derivatives could optionally be added to compositions for some other purpose, if desired. Nowhere is there even a scintilla of a suggestion that the required glycine derivatives could be added to an emulsion containing a significant amount of elastomer, and that the result would be a stable composition.

Stated another way, the applied art neither teaches, suggests, nor recognizes that adding the required glycine derivatives is a result effective variable with respect to stabilizing emulsions. Because of this, no motivation would have existed to add the required glycine derivatives to the claimed compositions, let alone to add the required glycine derivatives to the claimed compositions and then to optimize their concentration to effect composition stabilization. Nothing in the applied art would lead one skilled in the art to this invention.

In this regard, Applicants note the attached precedential opinion from the Board of Patent Appeals and Interferences in *Ex parte Whalen* (Tab A). In *Whalen*, the

Examiner's obviousness rejection was based on the reasoning that a person of ordinary skill in the art would have been motivated to optimize a specific property of prior art embolizing compositions (viscosity) because he would have had a reasonable expectation of success in achieving the safest clinical outcome and avoiding transvenous passage of the embolizing composition. (Pages 13-14). The Board rejected this reasoning, and concluded that the Examiner had not made out a *prima facie* case of obviousness.

The Board began by noting that "while discovery of an optimum value of a variable in a normal process is normally obvious, this is not always the case. ***One exception to the rule is where the parameter optimized was not recognized in the prior art as one that would affect the results.***" (Page 14)(emphasis added).

The Board explained that the Examiner had not pointed to any teaching in the cited references, or had not provided any reasoning based on scientific reasoning, that would support the conclusion that it would have been obvious to optimize the prior art embolizing compositions by increasing viscosity to the levels required by the claims.

Following *Whalen*, it is clear that the applied art does not render obvious the claimed stable compositions having a stabilizing effective amount of the required glycine derivatives present. None of the applied art teaches, suggests or recognizes the importance of having the specified glycine derivative present in an emulsion which also contains a significant amount of elastomer and a hydrophilic polymer, or the beneficial stabilizing effect that such glycine derivatives would have on these compositions. Applicants made this discovery. In the words of *Whalen*, because the applied art does not recognize that including the required glycine derivatives in an effective amount improves the stability of such compositions, the inclusion

of the required glycine derivatives in effective amounts is not a parameter that can be “optimized” under the law.

Furthermore, no apparent reason to supplement the broad, general teachings of the applied art exists to ensure that a stabilizing effective amount of the required glycine derivatives would be added to an emulsion which contains a significant amount of elastomer and a hydrophilic polymer (just as no apparent reason to increase viscosity existed in *Whalen*).

Robinson neither teaches nor suggests the presence of the required glycines. The Office has previously recognized this deficiency.

The Office Action recognized that Lorant, like Robinson, neither teaches nor suggests the claimed glycines (See, Office Action at page 7), meaning that Lorant cannot teach or suggest the claimed invention.

Thus, by themselves, neither of the primary references teaches or suggests the claimed invention.

The secondary references, Stoltz and Fontinos, do not compensate for Robinson’s and Lorant’s deficiencies. No motivation would have existed to combine these references with the primary references with the expectation that a stable, acceptable emulsion would result.

For example, the fact that Robinson states over the course of 20 pages (pages 41-60) that additional active agents can be added to his compositions does not teach or suggest the claimed invention either --- Robinson’s disclosure is so broad and general that one skilled in the art would not have been motivated to add the required lipophilic glycine compounds to Robinson’s compositions with a reasonable expectation that an acceptable composition would result (particularly given solubility issues), let alone to add the required glycine compounds

in an amount sufficient to stabilize an emulsion. For at least this reason, no motivation would have existed to combine Robinson and Stoltz to yield the claimed invention.

Similarly, the combination of Lorant and Fontinos does not yield the claimed invention. Lorant is silent concerning the claimed glycine compounds. Fontinos relates to a patch or pad. Nothing in either of these references would lead one skilled in the art to add an emulsion stabilizing effective amount of the required glycine compound to Lorant's compositions. That is, given that Fontinos' patches or pads are so structurally different from Lorant's compositions, no teaching, suggestion or motivation would have existed to add an emulsion stabilizing effective amount of the claimed glycine compounds to Lorant's compositions with the expectation that a stable emulsion would result.

In short, the applied art would not have led one of ordinary skill in the art to optimize the required glycine derivative ingredients in such a way as to produce stable emulsions which contain a significant amount of elastomer and a hydrophilic polymer.

Accordingly, and for at least the above reasons, no *prima facie* case of obviousness exists in the present case.

For all of the above reasons, Applicants respectfully request reconsideration and withdrawal of all pending rejections under 35 U.S.C. § 103.

The Office Action also rejected claims 1, 6 and 8-20 under 35 U.S.C. § 112, asserting that the phrases "dispersed in an oily phase" and "amount sufficient to disperse the elastomeric organopolysiloxane in the oily phase" do not satisfy the written description requirement and render the claims indefinite, respectively. Applicants respectfully submit that the above amendments to the claims have rendered these rejections moot, and that these rejections should be withdrawn.

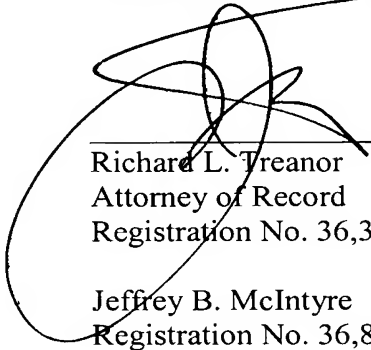
Application No. 10/685,505
Response to Office Action dated February 13, 2009

Furthermore, Applicants respectfully submit that the phrase “effective amount” in patent claims is a well-recognized, well-understood phrase in claims. See, *Abbott Labs. v. Baxter Pharmaceutical Products* (attached as Tab B). As such, this phrase, and claims containing this phrase, satisfy 35 U.S.C. § 112.

Applicants believe that the present application is in condition for allowance. Prompt and favorable consideration is earnestly solicited.

Respectfully submitted,

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